

Defendants"), alleging that the Defendants violated federal and state False Claims Acts. The Defendants move to dismiss Relator's and the States' complaints.

A. Procedural Posture

Relator filed the original qui tam action in June 2006, and subsequently filed her Third Amended Complaint ("Relator's Complaint") in December 2009, bringing claims on behalf of herself, the United States, Georgia, and New Mexico. In September 2009, the United States filed a Notice of Non-Intervention At This Time. Fifteen States and the District of Columbia (collectively, the "States"), filed a separate complaint in intervention in October 2009, and filed a First Amended Complaint in December 2009 ("States' Complaint"). Since then, several states have voluntarily dismissed their claims, including Delaware, Florida, Louisiana, Nevada, New Hampshire, and Texas.

In February 2010, the Court granted Amgen's motion to stay and sever Counts VII and VIII of Relator's Complaint. The Defendants also moved to dismiss Counts I-VI of Relator's Complaint and the States' Complaint. At oral argument on March 11, 2010, the Court dismissed the States' Complaint and made other tentative rulings. Afterwards, the Defendants submitted a Motion for Clarification and Reconsideration Regarding the Court's March 11, 2010 Ruling, asking the Court to consider dismissing Counts I and II of Relator's Complaint. In response, the Plaintiffs filed an Opposition and the United States filed a Statement of Interest. The Defendants also filed a Motion for

Clarification With Respect to Count II of Relator's Complaint, to which Relator filed an Opposition.

B. Facts As Alleged

The Plaintiffs allege that the Defendants violated state and federal False Claims Acts by causing providers to present false Medicare and Medicaid claims to the government and by conspiring to get false claims paid by the government. The Plaintiffs' complaints each contains parallel allegations, and each complaint incorporates the other by reference.

First, the Plaintiffs claim that the Defendants used various types of kickbacks to induce providers to purchase Aranesp, a drug manufactured by Amgen intended for treatment of anemia associated with chronic kidney disease and chemotherapy. One such kickback took the form of "excess overfill," i.e., dosages of liquid Aranesp that Amgen included in its single-dose vials, which were in excess of the amount necessary to withdraw the labeled dosage or the amount recommended by the United States Pharmacopoeia ("USP"). This excess overfill was akin to a built-in free sample for which the Defendants encouraged providers all over the country to bill, even when the extra Aranesp was either never administered or was administered in medically unnecessary cases. The free overfill created the potential for providers to profit from excess reimbursement and constituted an illegal kickback.

The Plaintiffs also allege that the Defendants gave kickbacks to providers in the form of sham consulting agreements,

all-expense paid retreats, free services, and price concessions. Amgen funded these kickbacks by paying monies to INN, disguised as Group Purchasing Organization ("GPO") administrative fees. INN and ASD would then pass such monies to providers as various forms of kickbacks. The Defendants' provision of all such kickbacks caused providers falsely to certify that they were in compliance with federal and state anti-kickback statutes when seeking reimbursement, and caused federal and state governments to pay claims they otherwise would not have paid.

Second, the Plaintiffs claim that Amgen reported an inflated Average Sales Price ("ASP") for Aranesp to the Medicare and Medicaid programs. The federal and state governments base the reimbursement rate for a particular drug on a pharmaceutical company's reported ASP. Although companies are not required to discount bona fide fees (such as GPO administrative fees) in their ASP calculation, they are required to discount price concessions given to customers. The fees Amgen paid to INN and ASD did not constitute bona fide fees and should have been discounted from Aranesp's ASP because they were passed through to providers as price concessions. Amgen failed to discount the price concessions, thereby causing federal and state governments to overpay for Aranesp claims.

Third, the Plaintiffs claim that the Defendants conspired to violate federal and state False Claims Acts by agreeing to engage in the above fraudulent conduct with an intent to cause false claims to be presented to the government.

Finally, several of the States bring state claims against the Defendants, including common law fraud and unjust enrichment.

II. ANALYSIS

The Defendants move to dismiss the Plaintiffs' complaints, arguing that the first-to-file rule bars Relator's claims and that the Plaintiffs fail to state a claim upon which relief may be granted. For the reasons discussed infra, the Defendants' motions to dismiss both complaints are allowed.¹

A. False Claims Act

The federal False Claims Act (the "Act"), 31 U.S.C. §§ 3729 et. seq., prohibits false or fraudulent claims for payment to the federal government and permits civil actions based on such claims to be brought by the Attorney General or by private individuals, called "relators," acting in the government's name, 31 U.S.C. § 3730 (a)-(c). Where the government elects not to intervene, the so-called qui tam plaintiff may proceed with the action as the government's assignee. Under the Act, liability attaches to a "false or fraudulent claim for payment," a "false record or statement [made] to get a false or fraudulent claim paid," or a "conspir[acy] to defraud the Government by getting a false or fraudulent claim . . . paid." 31 U.S.C. § 3729(a)(1)-(a)(3) (2008), amended by 31 U.S.C. § 3729(a) (2009).

¹ This holding deviates in part from the Court's tentative rulings rendered from the bench at the March 11, 2010 hearing. Each ruling in this memorandum and order that differs from the Court's tentative rulings will be noted.

B. First-to-File Bar

As an initial matter, the Defendants claim that the Court lacks subject matter jurisdiction over Counts I and II of Relator's Complaint because her federal claims are barred by the first-to-file rule.

1. Legal Standard

"The threshold question in a False Claims Act case is whether the statute bars jurisdiction." United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 (1st Cir. 2007). Under the Act's first-to-file bar, "when a person brings [a qui tam] action . . . , no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). "The first-to-file bar furthers the policy of the [False Claims Act] in that the first-filed claim provides the government notice of the essential facts of an alleged fraud, while the first-to-file bar stops repetitive claims." In re Pharm. Indus. Average Wholesale Price Litig., 2008 WL 2778808, at *2 (D. Mass. July 15, 2008) (Saris, J.) (internal quotation marks omitted).

In United States ex rel. Duxbury v. Ortho Biotech Prods., 579 F.3d 13 (1st Cir. 2009), the First Circuit followed the trend of other circuits and held that the first-to-file rule bars "'a later allegation [if it] states all the **essential facts** of a previously-filed claim' or 'the same **elements** of a fraud described in an earlier suit.'" 579 F.3d at 32 (quoting United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs.,

Inc., 149 F.3d 227, 232-33 (3d Cir. 1998)). Under this essential facts standard, "§ 3730(b)(5) can still bar a later claim, even if that claim incorporates somewhat different details." Id. (internal quotation marks omitted).

2. Application to the Plaintiffs' Complaints

a. Count I: Violation of Federal False Claims Act by Offering Kickbacks to Providers

In Count I, Relator alleges that the Defendants induced providers to purchase Aranesp with various types of kickbacks, thereby causing providers to present false certifications to the federal government. Rel. Compl. ¶¶ 154-64 [Doc. No. 113]. As discussed below, Relator's Count I is barred in part due to the first-to-file rule.

(1) Overfill Scheme

While Amgen does not argue that Relator's overfill allegations are barred by the first-to-file rule, the ABC Defendants do so contend. The ABC Defendants argue that a previous complaint already has alleged free Aranesp samples that providers billed to the government. ABC Defs.' Mem. Supp. Mot. Dismiss Rel. Compl. 4 (citing Ex. E ¶¶ 97-101) [Doc. No. 141]. The general allegations in the prior complaint, however, do not encompass the detailed methodology and widespread scheme of overfill marketing described in Relator's Complaint. Here, Relator alleges that: Amgen included in its single-dose vials of Aranesp extra dosages of the drug that were in excess of the amount necessary to withdraw the labeled dosage and the amount recommended by the USP; the Medicare program will reimburse for

the amount of the drug administered where the amount administered is in excess of the labeled dosage; and that in an extensive national promotion scheme, which included seminars and private visits teaching providers how to fill out Medicare forms, Amgen and INN encouraged providers to administer overfill even where it was medically unnecessary so that providers could capture the profit, or to claim reimbursement for overfill that was never administered. See Rel. Compl. ¶¶ 78-99.

The essential facts of this fraudulent scheme previously have not been alleged. The First Circuit's holding in Duxbury is instructive. There, the original complaint and a later complaint contained "significant similarities," both alleging that the pharmaceutical company promoted an off-label dosing regimen to increase Medicare payments, causing false claims to be filed. Duxbury, 579 F.3d at 33. The First Circuit, however, explained that the complaints "differ in one crucial respect," as the later complaint "contained a number of allegations that discuss, in significant detail, OBP's promotion of the 'off-label' use" and alleged six different promotion methods. Id. Because the original complaint alleged only one method of off-label promotion, the court held that the original complaint "fail[ed] to allege the 'essential facts' of the 'off-label' **promotion scheme** contained in the [later complaint]." Id.

Here, Relator's Complaint is not only the first to plead a widespread promotion scheme of encouraging and teaching providers to bill for overfill, but the first to allege a new methodology

of inducing providers with free samples in the form of overfill. Thus, the first-to-file rule does not bar this claim.

(2) Sham Consultancy Agreements, Retreats, and Services

Relator's Count I allegations that Defendants induced Aranesp sales with sham consultancy agreements, all-expense paid weekend retreats, and other free services are barred as against Amgen because previous complaints amply have pled such essential facts regarding Amgen. See Mayer Decl., Ex. 3 ¶¶ 54, 59, 62-64; Ex. 2 ¶ 65; Ex. 1 ¶¶ 102-03. Such allegations against the ABC Defendants, however, are not so barred as the previous complaints make no mention of INN or ASD's involvement (or that of their corporate affiliates) in providing such kickbacks. Here, Relator alleges that although the kickbacks were often ultimately funded by Amgen, INN directly organized and offered the retreats and free practice assessments, and disguised the kickbacks as INN's GPO services. See, e.g., Rel. Compl. ¶¶ 106, 116-18, 121-22. Previous complaints do not allege such essential facts. Therefore, such claims against the ABC Defendants are not barred.² See In re Natural Gas Royalties Qui Tam Litig., 566 F.3d 956, 962 (10th Cir. 2009) ("The identity of a defendant constitutes a material element of a fraud claim").

² At oral argument, the Court tentatively ruled that Relator's Count I kickback claims based on sham consultancy agreements, weekend retreats, and other free services were barred by the first-to-file rule as against all the Defendants. After further consideration, however, the Court has determined that the analysis in the text is correct.

(3) Discounts via Pass-Through Administrative Fees and ASP Inflation

Encompassed in Relator's Count I are also claims that Amgen funneled money to INN and ASD under the guise of "administrative fees," which INN and ASD then passed along to providers in the form of price concessions, and that Amgen failed to include such payments in its ASP calculations. Rel. Compl. ¶¶ 103, 106, 110, 129-31. The Defendants, however, have cited to earlier complaints where such a scheme amply has been pled. See Mayer Decl., Ex. 1 ¶¶ 114, 122, 124-25, 129, 133-38, 140.

In response, Relator argues that because the previously-filed complaints did not specifically make such allegations against INN or ASD, Relator's pass-through discount claims, at least as against the ABC Defendants, are not barred. In oral argument, Relator cited to In re Natural Gas Royalties Qui Tam Litig., 566 F.3d 956, 962 (10th Cir. 2009), which held that "[t]he identity of a defendant constitutes a material element of a fraud claim."

This case differs from In re Natural Gas Royalties, however, because the same allegations regarding this pass-through discount and ASP-inflation scheme previously have been made against corporate affiliates of INN and ASD. See Mayer Decl., Ex. 1 ¶¶ 114, 122, 124-25, 129, 133-38, 140. Where almost identical facts have been alleged against the corporate affiliates and the parent corporations of INN and ASD, the government likely had adequate notice of the scheme and thus such claims should be barred. In re Natural Gas Royalties, 566 F.3d at 962 ("Cases involving

parents, subsidiaries, and other corporate affiliates might . . . require deviations from the general requirement that claims must share common defendants in order to trigger the first-to-file bar."); Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1280 n.4 (10th Cir. 2004) (holding that naming corporate affiliates of previously-named defendant in the same scheme does not avoid the first-to-file bar); United States ex. rel. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214, 218 (D.C. Cir. 2003) (holding that later-filed complaint's allegations against a specific subsidiary were already encompassed in allegations in first-filed complaint against the parent corporation). Therefore, Relator's claims regarding Amgen's inflation of Aranesp's ASP and pass-through discount scheme involving INN and ASD are barred as against all the Defendants.

b. Count II: Violating Federal False Claims Act by Conspiring to Get False Claims Paid

While the Defendants concede that no prior complaints allege a legal theory of conspiracy, they still contend that the "essential facts" of Relator's conspiracy claim previously have been pled. Amgen's Mem. Supp. Mot. Dismiss Counts I-VI of Rel. Compl. 8 (citing Mayer Decl., Ex. 2 ¶¶ 80-89) [Doc. No. 140]. Relator's Complaint, however, contains essential elements of a fraudulent scheme absent from the complaints cited by Amgen. The Plaintiffs allege that: INN passed itself off as a neutral GPO, concealing from its member providers INN's close relationship with Amgen; INN visited providers ostensibly to help them find billing errors or ways to increase revenue, but actually shared

with Amgen confidential information gained therefrom, so that INN and Amgen could tailor their marketing strategy for each practice; and that the Defendants were "triangulating customers: ASD, Amgen and INN were all targeting the customer from slightly different angles and the customer had no idea that the different reps were talking to each other and sharing information, and that each company was attempting to direct business to the other(s)." Rel. Compl. ¶¶ 105, 116-20.

Relator also pleads that Amgen and the ABC Defendants "knowingly agreed and conspired to defraud the federal and state governments by having false and fraudulent statements, certifications, and claims for Aranesp submitted to, paid and approved by Government Health Care Program[s]." Id. ¶ 167. Because Relator's Complaint contains essential facts and elements of a conspiracy to defraud the government not alleged in previous complaints, Count II is not barred by the first-to-file rule. Further, because the conspiracy is a different scheme containing different elements and additional essential facts, Relator is not jurisdictionally barred from relying upon any of the above allegations regarding kickbacks or the inflation of the ASP to support her conspiracy claim, even if such allegations are barred in support of her Count I presentment claim.

c. Counts III, IV, V, and VI: Violations of Georgia and New Mexico State False Claims Acts

The ABC Defendants concede there is no first-to-file rule in Georgia, but claim that because the rest of Relator's federal

claims are jurisdictionally barred, the Court cannot exercise supplemental jurisdiction over Counts III and IV. This argument is moot as Relator's federal claims are not entirely barred by the first-to-file rule. While the ABC Defendants argue that New Mexico's first-to-file rule bars Counts V and VI, ABC Defs.' Mem. Supp. Mot. Dismiss Rel. Compl. 4 n.2 (citing N.M. Stat. Ann. § 27-14-10, which prohibits a person from bringing claim based on New Mexico Medicaid False Claims Act based on allegations in prior filed action in which New Mexico is already a party), they point to no previously-filed complaints that include the essential facts pled in Relator's Complaint where New Mexico is a party. Thus, Counts V and VI are not jurisdictionally barred.

C. Failure to State a Claim Under Fed. R. Civ. P. 12(b)(6)

1. Legal Standards

a. Motion to Dismiss Standard

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) challenges a complaint on the basis that it fails to state a claim upon which relief can be granted. To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). A pleading that merely offers "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" is insufficient. Id. at 555.

Since the federal and state False Claims Acts create statutory torts, the inquiry focuses on whether the Plaintiffs

have alleged facts that fit within the specific contours of these statutes.

b. Presentment and Conspiracy Liability under the False Claims Act

The federal False Claims Act and the parallel state False Claims Acts of the Plaintiff States impose liability upon persons who knowingly present or cause to be presented to the government a false claim for payment (so-called "presentment" liability), as well as persons who conspire to defraud the government by getting a false or fraudulent claim allowed. 31 U.S.C. § 3729(a)(1), (a)(3) (2008), amended by 31 U.S.C. § 3729(a) (2009). Here, the Plaintiffs allege that the Defendants are liable under both theories.

As this Court has held, to state a federal claim under the "presentment" theory, "an individual must allege that the accused: (1) knowingly presented or caused to be presented, (2) a false claim, (3) to the United States government, (4) knowing its falsity, (5) which was material, (6) seeking payment from the federal treasury." United States ex rel. Hutcheson v. Blackstone Med., Inc., -- F. Supp. 2d --, 2010 WL 938361, at *10 (D. Mass. Mar. 12, 2010) (citing United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004) and United States v. Data Translation, Inc., 984 F.2d 1256, 1267 (1st Cir. 1992)). While conspiracy liability does not require presentment, it does require that the defendants "intended to defraud the government [by getting false claims paid]" and "agreed that the false record or statement would have a material effect on the

Government's decision to pay the false or fraudulent claim." United States ex. rel. Gagne v. City of Worcester, 565 F.3d 40, 46 (1st Cir. 2009); see 31 U.S.C. § 3729(a)(3) (2008), amended by 31 U.S.C. § 3729(a) (2009).

2. False Certification Liability: A "False" Claim

Under both presentment and conspiracy liability, "a false claim" must be alleged. This is because the Supreme Court has made it clear that the False Claims Act was not designed to reach all types of fraud performed upon the government. United States v. McNinch, 356 U.S. 595, 599 (1958). "[T]he statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'" United States v. Rivera, 55 F.3d 703, 709 (1st Cir. 1995). Here, the ABC Defendants contend that the Plaintiffs fail to allege any such false claim for payment under an express or implied certification theory because compliance with state or federal anti-kickback statutes is simply not a condition of payment under Medicare or Medicaid. The Plaintiffs do not dispute that all of their claims rely on the false certification theory of liability.

a. Types of Falsity

There are three theories under which a claim may be "false or fraudulent" under the False Claims Act: (1) factual falsity, (2) legal falsity under an express certification theory, and (3) legal falsity under an implied certification theory. Hutcheson, 2010 WL 938361, at *11.

A "factually false claim" is one in which the goods or services provided are either incorrectly described or which makes a claim for a good or service never provided. Id. (citing Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001)). Here, the Plaintiffs do not base their theory of liability on factual falsity, but rather on legal falsity.

A "legally false claim" occurs when a party certifies compliance with a statute or regulation but the party is not actually in compliance with the statute or regulation. Hutcheson, 2010 WL 938361, at *11 (collecting cases from other circuits). To state a legally false claim, compliance with the particular statute must be a precondition of payment. Id. A claim may be legally false under either an express certification theory or an implied certification theory. Id.

A claim is legally false under an express certification theory when the party making the claim for payment expressly represents compliance with a statute or regulation, and such compliance is a precondition to payment. Id. at 12. No specific form of "certification" is required, so long as the statement of compliance is knowingly false when it was made. Id. (citing United States ex rel. Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1172 (9th Cir. 2006)).

A claim is legally false under the implied certification theory when a claimant makes no express statement regarding compliance with a statute or regulation, but by submitting a claim for payment, the claimant implies that it has complied with

any stated preconditions of payment. Id. In Hutcheson, this Court adopted the logic of the Second Circuit and ruled that implied certification applies only where preconditions of payment are **expressly** stated in the relevant statute or regulations. See id. (citing Mikes, 274 F.3d at 700).

b. Application to the Plaintiffs' Complaints

(1) Express Certification Theory

Relator contends that Counts I and II on behalf of the United States state a "legally false" claim under the express certification theory. The ABC Defendants, however, argue that the language in the Medicare Enrollment Form³, which providers are required to fill out and sign in order to participate in the Medicare program, does not qualify as an express certification. The provider agreement states in relevant part: "I agree to abide by the Medicare laws . . . that apply to [me]. . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws,

³ To be eligible for Medicare reimbursement, providers must sign a certification on Form CMS-855A or Form CMS-855I, which contain nearly identical language. The certification on Form CMS-855A reads:

I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all application conditions of participation in Medicare.

regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law).” Medicare Enrollment Forms CMS-855A and CMS-855I.

The ABC Defendants assert that such language is only an agreement to comply with the anti-kickback statute in the future and not an express certification that one has complied with the anti-kickback statute. In support, they cite United States ex rel. Kennedy v. Aventis Pharms., Inc., 610 F. Supp. 2d 938 (N.D. Ill. 2009), where the court held that “no express false certification of compliance with the anti-kickback statute” had been made based on the provider agreement, as “[the relators] allege only that the hospitals promised they would comply with the statute and affirmed their understanding that if they did not do so, they would be ineligible for Medicare participation.” 610 F. Supp. 2d at 946. The court characterized the enrollment certification as a “forward-looking statement - a promise or undertaking - not a false representation” and ruled that relators had not identified “any certification [of compliance with the anti-kickback statute] . . . in connection with a Medicare claim.” Id. In a post-hearing brief, the Defendants also point to this Court’s language in Hutcheson, which stated that “[a] claim is legally false under an express certification theory when the party making the claim expressly states that it **has complied** with the applicable statutes’ regulations.” Defs.’ Joint Mot. Clarification and Reconsideration 2 (citing Hutcheson, 2010 WL 938361, at *12) (emphasis added). They reason that because this

Court's definition of express certification requires a certification of **past** compliance with the anti-kickback Statute, there is no false claim here.

After careful consideration of the Defendants' argument, the Court sees no reason why an express certification of compliance with a particular statute cannot be prospective, as long as it is knowingly false when made. In Hutcheson, the Court did not intend to imply that an express certification of compliance must always state that a provider "**has**" complied with a statute in order to trigger False Claims liability. For example, one can imagine a regulatory scheme in which a provider is required, as a condition of participation or payment, expressly to certify that the transactions underlying all claims that the provider will submit in the future "will comply" with a particular statute. There is no reason why such an explicit certification of future compliance cannot be the basis of False Claims Act liability if the provider makes such a certification knowing that it will violate the statute, and later submits claims which are not in compliance with the statute.

As the Seventh Circuit has stated, the False Claims Act requires a "causal rather than a temporal connection between fraud and payment. . . . If a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork." United States ex rel. Main v. Oakland City Univ., 426 F.3d 914, 916 (7th Cir. 2005); see also United States ex rel.

Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1174 (9th Cir. 2006) (holding university liable under false certification theory where university certified, as a condition of participation in federal loan program, that it "will comply" instead of "has complied" with ban on incentive compensation because "[such] grammatical haggling is unmoored in the law.").

Such an interpretation of falsity comports with Congressional intent. While the False Claims Act is not intended to reach fraudulent conduct where no claim for payment is made, McNinch, 356 U.S. at 599, where such a claim actually is made on the federal treasury, the Supreme Court has suggested that the Act should be construed broadly, United States v. Neifert-White Co., 390 U.S. 228, 232-33 (1968) (stating that "the Act was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government" and that "the objective of Congress in enacting the False Claims Act was broadly to protect the funds and property of the Government from fraudulent claims, regardless of the particular form, or function, of the government instrumentality upon which such claims were made") (internal quotation marks omitted). Moreover, Congress's statement after the 1986 amendments to the Act that "each and every claim submitted under a contract, loan guarantee, or other agreement which was originally obtained by means of false statements or other corrupt or fraudulent conduct, or in violation of any statute or applicable regulation, constitutes a false claim," S. Rep. No. 99-345, at 9, as reprinted in 1986

U.S.C.C.A.N. 5266, 5274, demonstrates an intent that the Act be broadly construed. See Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 786 (4th Cir. 1999).

In this case, the Medicare Enrollment Form essentially contains a prospective express certification that the provider will comply with Medicare laws including the anti-kickback statute and acknowledges that compliance with the anti-kickback statute is a condition of payment. Providers must complete the enrollment form and sign the certification to be eligible for Medicare reimbursement. See 42 C.F.R. § 424.510. The Defendants argue in part that this is an express certification only "in connection with enrollment" (rather than "in connection with a claim") and categorizes the promise to comply with anti-kickback as a condition of participation rather than payment. This argument, however, is undercut by the explicit language in the form that the provider "understand[s] that **payment of a claim . . . is conditioned upon the claim . . . comply[ing] with . . . the Federal anti-kickback statute.**" In the context of the express certification theory, such semantic hair-splitting where the provider clearly has notice that compliance with the anti-kickback statute is a condition of payment, is contrary to Congress's intent that the Act reach all types of fraud where the government fisc is affected.

Thus, the problem here is not necessarily the "forward-looking" language of the certification or that the certification is contained in an enrollment form instead of a claim form, but

rather that the Plaintiffs have not alleged that providers expressly made such statements knowing their falsity. The Plaintiffs do not allege that when the providers signed the enrollment forms, they knew that they would be accepting kickbacks from the Defendants in violation of the anti-kickback statute. Without such pleading, there can be no "false claim." Therefore, Relator's Complaint fails to state a legally false claim under the express certification theory.⁴

⁴ At oral argument, the Court tentatively ruled that Counts I and II of Relator's Complaint stated a legally false claim under the express certification theory. For the reasons stated above, the Court now holds that Relator's Complaint fails to state such a claim.

Moreover, Relator's pleadings suffer the same fatal flaw under a theory of False Claims liability based on promissory fraud, sometimes called fraud-in-the-inducement. Courts, including the Supreme Court, have held that where a contract or extension of government benefit was originally obtained through false statements or fraudulent conduct, False Claims liability can attach to each claim submitted under the contract even if the contract is fully performed. See, e.g., United States ex rel. Marcus v. Hess, 317 U.S. 537, 542 (1943) (holding contractors liable under False Claims Act for claims submitted under government contracts that defendants obtained via collusive bidding); United States ex rel. Main v. Oakland City Univ., 426 F.3d 914, 917 (7th Cir. 2005) ("[M]aking a promise that one intends not to keep is fraud . . . if the [defendant] . . . told the Department that it would comply, while planning to do otherwise, it is exposed to penalties under the False Claims Act."). Some courts have applied this theory in the context of educational institutions that are required to make certifications when seeking federal subsidies under Title IV. See Main, 426 F.3d at 916; see also United States ex rel. Hendow v. Univ. of Phoenix, 461 F.3d 1166 (9th Cir. 2006) (noting "that the promissory fraud theory, in substance, is not so different from the false certification theory, and even requires the same elements . . . a claim must be false, and . . . that falsity must be knowingly perpetrated"). In the Title IV context, educational institutions must enter into a participation agreement with the Department of Education, certifying that they will abide by the ban on incentive compensation. The Seventh Circuit has held that where a university certifies that it will comply with the ban never intending to comply, and such a certification is a

The States' Complaint also fails to state a legally false claim under the express certification theory. In arguing that providers must expressly certify compliance with anti-kickback statutes, the States cite to the sample enrollment forms attached to the States' Complaint. Rel.'s Opp'n to ABC's Mot. Dismiss 12 n.17 [Doc. No. 160]; see States Compl. ¶ 39 and Ex. A [Doc. No. 112]. Unlike the Medicare CMS Forms 855A or 855I, however, the state Medicaid provider enrollment forms contain no language stating that providers must be in compliance with state or federal anti-kickback statutes.

The States attempt to circumvent this deficiency by citing to language in the provider agreements requiring "compliance with applicable state and federal laws" or an agreement "to not engage in or commit fraud or abuse." Rel.'s Opp'n to ABC's Mot. Dismiss 12 n.17. Such broad language requiring compliance with "all applicable state and federal laws" is insufficient to constitute an express certification of compliance with anti-kickback statutes. See United States ex. rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1218-19 (10th Cir. 2008) (holding that certification that represented compliance with

prerequisite to participation and thus payment, the false statement renders all subsequent claims under the participation agreement false. Maine, 426 F.3d at 917. Similarly here, Medicare providers must sign the certification contained in the enrollment form to participate in the Medicare program and receive payments. If a provider so certifies never intending to comply with the anti-kickback statute, the original false certification arguably renders all subsequent claims false under the promissory fraud theory. As explained above, however, the Plaintiffs have not alleged that the providers made such certifications knowing their falsity.

"laws and regulations regarding the provision of health care services" was too general to impose liability because such broad liability conflicts with the principle that not any false statement imposes liability under the False Claims Act, but only those which are material and would have "[led] the government to make a payment which it would not otherwise have made").

Therefore, Relator and the States have failed to state a claim under the theory that the Defendants, by inducing Aranesp sales with kickbacks, caused providers falsely and expressly to certify compliance with federal and state anti-kickback statutes.

(2) Implied Certification Theory

The Plaintiffs also contend that the complaints state a "false" claim under the implied certification theory. This Court, however, has held that liability based on an implied certification theory requires that the relevant statute or regulation expressly state that compliance with a particular requirement is a precondition of payment. Hutcheson, 2010 WL 938361, at *12 (citing Mikes, 274 F.3d at 700). This is because the implied certification theory is "based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." Mikes, 274 F.3d at 699. In essence, even though the defendant makes no express statement regarding compliance, the law treats the defendant as though it had fraudulently represented compliance simply because compliance is a precondition to payment. Where courts constructively impose

scienter based on a defendant's submission of a claim, adequate notice should be given that compliance is a precondition to payment by an express statement in the relevant statute or regulation.

With respect to Counts I and II of Relator's Complaint, the Defendants correctly state that no statute or regulation expressly requires compliance with anti-kickback statutes as a condition of payment.⁵ Moreover, while exclusion from the Medicare program is mandatory if a provider is convicted of violating the anti-kickback statute, 42 U.S.C. § 1320a-7(a)(1), exclusion is only permissive for a provider determined by the Secretary of Health and Human Services in an administrative proceeding to have committed an act that would violate the anti-kickback statute, 42 U.S.C. § 1320a-7(b)(7). The only shaft left in Relator's quiver is the enrollment agreement, but this Court has held that in the context of implied certification, "a precondition [of payment] cannot be hidden in an enrollment form." Hutcheson, 2010 WL 938361, at *15.

Most of the cases Relator cites for the proposition that Medicare providers impliedly certify compliance with the anti-kickback statute either do not explain why they so hold, involve

⁵ As the Plaintiffs and the United States point out in their post-hearing briefs, the federal anti-kickback statute, 42 U.S.C. § 1320a-7b, was recently amended. As of March 23, 2010, the anti-kickback statute includes language stating that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the False Claims Act]." Patient Protection and Affordable Care Act, Publ. L. No. 111-148, 124 Stat. 119 § 6402(f)(1) (2010).

parties who agree that failure to comply with anti-kickback statutes can be the basis of the implied certification theory, or conflate the implied certification theory with a materiality analysis.⁶ The Plaintiffs also cite Ab-Tech Constr., Inc. v. United States, 31 Fed. Cl. 429 (1994), aff'd, 57 F.3d 1084 (Fed. Cir. 1995), where the court held that Ab-Tech's submission of payment vouchers was an implied certification of its continuing adherence to the requirements for participation in a federal small business program, the central purpose of which was to assist minority-owned enterprises in gaining business experience. 31 Fed. Cl. at 434. There, Ab-Tech failed to obtain approval for its subcontract as required by the participation agreement. Although the court characterized the claim as false because of Ab-Tech's "implied certification," it seemed more concerned with

⁶ See, e.g., McNutt ex rel. United States v. Haleyville Med. Supplies, Inc., 423 F.3d 1256 (11th Cir. 2005) (ruling that Medicare provider agreement created basis for False Claims Act liability where "the [defendants] [did] not dispute that their failure to comply with the Statute, if true, disqualified them from receiving payment as part of a Medicare program"); United States ex rel. Barrett v. Columbia/HCA Healthcare Corp., 251 F. Supp. 2d 28, 33 (D.D.C. 2003) (holding that defendants impliedly certified compliance with anti-kickback statute because compliance with anti-kickback "would affect the government's decision to pay"); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 12, 18 (D. Mass. 2007) (Saris, J.) (holding that "[b]ecause the FCA is a remedial statute that must be broadly read" and defendants conceded that Medicare providers expressly certify compliance with the anti-kickback statute, "the [False Claims Act] is violated when a Medicaid claim is presented . . . in violation of the Anti-Kickback statute, even if there is no express certification of compliance with the statute"); United States ex rel. Pogue v. American Healthcorp, Inc., 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996) (holding that implied certification theory applied because relator alleged that government would not have paid claims had it been aware of alleged kickback violations).

Ab-Tech's concealment of the fact that it had contracted with a non-minority business, contrary to the entire purpose of the program:

Ab-Tech not only dishonored the terms of its agreement with that agency **but, more importantly**, caused the Government to pay out funds in the mistaken belief that it was furthering the aims of the 8(a) program. In short, the Government was duped by Ab-Tech's **active concealment of a fact vital to the integrity of [the] program**. The withholding of such information - information critical to the decision to pay - is the essence of a false claim.

Id. (emphasis added). In the present context, however, enforcement of the anti-kickback statute cannot be said to be the central purpose of the Medicare program. Moreover, as the Second Circuit has cautioned, "[t]he Ab-Tech rationale . . . does not fit comfortably into the health care context because the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations - but rather only those regulations that are a precondition to payment - and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the Act's reach." Mikes, 274 F.3d at 699. In the absence of an express statute or regulation declaring compliance with the anti-kickback statute to be a precondition of payment, the cases cited by the Plaintiffs do not persuade this Court to apply an implied certification theory here. Therefore, Counts I and II of Relator's Complaint fail to state a false claim under a theory of implied certification.

The States' Complaint and Counts III-VI of Relator's Complaint suffer from the same legal flaw. The States do not

allege or cite state law that expressly requires compliance with anti-kickback statutes as a condition of Medicaid reimbursement. Relator similarly makes no such allegations in support of her claims on behalf of New Mexico and Georgia. Therefore, the States' Complaint and Counts III-VI of Relator's Complaint fail to state a claim under the implied certification theory.

Because both Relator's and the States' complaints fail to state a legally false claim under the express or implied theories of certification, both complaints are dismissed.⁷

(3) Alternative Theories

The Plaintiffs' complaints and briefs focus solely on the Defendants' inducement of providers with kickbacks, including overfill, as the cause of providers' false certifications. See, e.g., Rel. Compl. ¶¶ 132, 137; States Compl. ¶¶ 90, 91, 95, 162. After a careful reading of both complaints, however, the Court notes that there appear to be a few allegations, albeit not fully developed and likely insufficient at this time, that may support alternative theories of liability under state and federal False Claims Acts.

⁷ At oral argument, the Court dismissed the States' Complaint and tentatively dismissed Counts III-VI of Relator's Complaint. The Court now holds for the above reasons that Counts I and II of Relator's Complaint are dismissed as well for failure to state a legally false claim under either an express or implied certification theory.

The Court recognizes, of course, that an esteemed colleague on this Court previously has held that Medicare requires providers affirmatively to certify that they have complied with the anti-kickback statute, and that Medicaid providers implicitly certify compliance with the anti-kickback statute. See In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 12, 18 (D. Mass. 2007) (Saris, J.).

The complaints contain allegations that may potentially support a theory of factual falsity, i.e., that the Defendants and their representatives encouraged providers to bill for overfill and claim reimbursement for dosages of Aranesp that were never administered. See, e.g., Rel. Compl. ¶¶ 83(b), 86, 96 (alleging that Defendants encouraged providers to record on patient charts that overfill dosages were administered even if they were never administered, and to submit claims for such unadministered overfill). In addition, based on similar allegations, there may be a claim of legal falsity under an express certification theory, involving providers who falsely certified that drugs were actually administered when they were not. See, e.g., States Compl., Ex. A at Delaware Provider Contract ¶ 3 ("The submission . . . of any claim . . . shall constitute certification . . . that the items or services were actually rendered."); Texas Medicaid Provider Agreement ¶ 1.3.3 ("All claims submitted by Provider must be for services actually rendered by Provider.").

Moreover, the complaints contain allegations that potentially could support another express certification theory, involving providers who expressly and falsely certified that their claims included only "medically necessary" supplies or services. See, e.g., States Compl., Ex. A at Delaware Provider Contract ¶ 3 ("The submission . . . of any claim for payment . . . shall constitute certification . . . that the items or services were . . . medically necessary."); Louisiana Provider Agreement ¶

10 ("I understand that services and/or supplies provided by me must be medically necessary and medically appropriate."); New York Certification Statement ("All care, services and supplies for which claim is made are medically necessary."). Both complaints contain some allegations that the Defendants encouraged providers to administer overfill which was not medically necessary and/or harmful to the patient so that providers could bill for such free overfill. See, e.g., Rel. Compl. ¶¶ 83, 90, 91; States Compl. ¶¶ 47-49, 87-89, 129.

Again, the allegations supporting such theories are likely insufficient at this time to meet the standard of Federal Rule of Civil Procedure 9(b). Moreover, the Plaintiffs have not argued such theories in their briefs or at the hearing.

3. Claims Against ABC and ABSG

ABC and ABSG argue that the complaints do not allege any wrongdoing on the part of either of those entities, and that allegations of corporate ownership without allegations supporting the piercing of the corporate veil are insufficient. ABC and ABSG correctly point out that the complaints do not allege the direct involvement of ABC and ABSG in the False Claims Act violations. The few pleadings that the Plaintiffs cite in their brief as allegations of direct involvement are insufficient and make only passing mention of each entity. See Rel. Compl. ¶¶ 17, 102, and 102 n.2; States Compl. ¶¶ 16, 186, 178. None suggest ABC and ABSG's "intimate involvement" with the fraudulent scheme contrary to the Plaintiffs' contention.

Moreover, the complaints describe ABC and ABSG as nothing more than the "parent corporations" of ASD and INN, and similarly describe ASD and INN as "wholly owned subsidiaries" of ABC and ABSG. See, e.g., States Compl. ¶¶ 16 ("INN is a wholly owned subsidiary of . . . ABSG, with its ultimate parent being . . . ABC."), 17 ("ASD . . . is wholly owned by ABSG."). The Plaintiffs concede that they make no attempt to pierce the corporate veil, and the complaints do not support the Plaintiffs' argument that ABC and ABSG are successors-in-interest to ASD or INN. Therefore, ABC and ABSG are dismissed from this action. See United States ex rel. Kneepkins v. Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 39 (D. Mass. 2000) (O'Toole, J.) ("Ownership - even total ownership - of a corporation does not by itself impart the corporation's liabilities to the owner, and that rule is not abated simply because the owner happens to be another corporation.").

III. CONCLUSION

Accordingly:

To the extent Count I of Relator's Third Amended Complaint is based on (1) kickbacks in forms other than the overfill scheme as against Defendant Amgen, (2) the pass-through administrative fee scheme as against all Defendants, and (3) ASP inflation as against all Defendants, it is DISMISSED because such claims are barred by the first-to-file rule and this deprives the Court of jurisdiction over these claims.

The remainder of Count I and Counts II-VI of Relator's Third Amended Complaint, as well as the claims in the States' First Amended Complaint based on false certifications regarding compliance with the anti-kickback statute, are DISMISSED WITHOUT PREJUDICE pursuant to Federal Rule of Civil Procedure 12(b)(6) because the complaints do not allege facts supporting a legally false claim under the express or implied certification theories.

Because the above claims are dismissed, the Court declines to exercise supplemental jurisdiction over the States' remaining False Claims Act claims based on the Defendants' inflation of Aranesp's ASP and the States' common law and other state claims.

ABC and ABSG are DISMISSED as parties to the action because the complaints fail to plead sufficient facts supporting that those entities were involved in the fraudulent scheme.

SO ORDERED.

/s/ William G. Young
WILLIAM G. YOUNG
DISTRICT JUDGE